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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,624	09/03/2004	Katsura Nozawa	08959.0009	1864

22852 7590 04/11/2007

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EXAMINER	
BALLARD, KIMBERLY A	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,624	NOZAWA ET AL.	
	Examiner	Art Unit	
	Kimberly A. Ballard	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3-8 and 19-21* is/are allowed.

6)☐ Claim(s) *9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 1, 4 and 7-11 have been amended, claims 2 and 12-18 have been canceled, and claims 19-21 have been added as requested in the response filed December 29, 2006.

Claims **1, 3-11** and **19-21** are pending and under examination in the instant office action.

Any objection or rejection of record regarding claim 2 or claim 18 is rendered moot in view of Applicant's cancellation of said claims.

Withdrawn Objections and/or Claim Rejections

The objection to claims 1 and 8-11, as set forth a page 3 of the 09/08/2006 office action is withdrawn in view of Applicant's amendments to the claims.

The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as set forth at page 4 of the previous office action, is withdrawn in view of Applicant's amendments to the claims.

The rejection of claims 1 and 3-7 under 35 U.S.C. 102(a), as being anticipated by Li et al. (*J Biol Chem*, December 2002; 277(50): 48410-48417), has been overcome in

view of the certified English translations of priority documents JP 2002-225114 and JP 2003-182989 provided by Applicant filed December 29, 2006.

The rejection of claims 1 and 3-8 under 35 U.S.C. 102(e), as being anticipated by US Patent No. 6,787,352 to Friddle et al., is withdrawn in view of Applicant's amendments to the claims.

The rejection of claims 8-11 under 35 U.S.C. 103(a) as being unpatentable over Mochizuki and Jiang (*Japanese Heart J*, 1998; 39(6): 707-714) in view of Harada et al. (*J Pharm Exp Therap*, 2000; 294(3): 1034-1042) as evidenced by Balasubramanyam et al. (*J Clin Invest*, 1994; 94: 2002-2008), is withdrawn in view of Applicant's amendments to the claims.

Maintained Claim Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 9-11 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,787,352 to Friddle et al. (issued 7 September 2004, filed 24 September 2001) is maintained for reasons of record.

In the response filed December 29, 2006, Applicants argue that nowhere does Friddle teach any methods directed to "screening for an inhibitor of leukocyte activation", "screening for a therapeutic agent for postischemic reperfusion injury and/or an inflammatory disease", or "manufacturing a pharmaceutical composition for treating postischemic reperfusion injury and/or inflammatory disease". Applicants assert that Friddle's disclosure is so broad that it essentially covers treatment of any disorder or disease, and therefore cannot anticipated the instantly claimed methods. Further, Applicants argue that Friddle does not teach that its "novel human proteins" (NHPs) are expressed in leukocytes, and therefore fails to teach inhibition of leukocyte activation as currently recited in claim 9.

Applicants' arguments have been fully considered but they are not persuasive.

In response to applicants' argument that there is no disclosure in Friddle et al. of screening methods for determining an inhibitor of leukocyte activation, for determining a therapeutic agent for post-ischemic reperfusion injury and/or an inflammatory disease, or for manufacturing a pharmaceutical composition for treatment of post-ischemic reperfusion injury and/or inflammatory disease, these recitations in claims 9-11 have not been given patentable weight because the recitations occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the

claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Friddle discloses that the novel human proteins (NHPs) of the invention share structural similarity with mammalian potassium dependent sodium-calcium exchanger proteins (see column 1, lines 37-41). As determined by a sequence database search, Friddle's SEQ ID NO: 2 is 100% identical to the instantly claimed SEQ ID NO: 4. Friddle et al. also teach expression vectors comprising polynucleotide encoding said polypeptide, as well as host cells comprising said expression vectors (see claims 6 and 7 of patent). Friddle further discloses methods for identifying compounds that act as agonists or antagonists (i.e., enhance or inhibit) of the disclosed protein's endogenous activity using purified preparations of the protein or cells expressing the protein (see column 2, lines 18-25, and column 13, lines 63-67). Based on the teachings of Friddle et al. noting that the disclosed NHPs bear structural similarity with mammalian potassium dependent sodium-calcium exchanger proteins, it would be well within the capability and knowledge of the skilled artisan to assay for such an ion-exchange activity in order to determine potential therapeutic agonist or antagonist compounds. Because there is nothing in the method steps of instant claim 9 to distinguish them over the teachings of Friddle, the recitation in step d that the substance would "inhibit[s] leukocyte activation" has been interpreted as an inherent property of an inhibitor substance of SEQ ID NO: 4, and therefore an antagonist compound found by Friddle's

disclosed screening method would also inherently be capable of inhibiting leukocytes, thus still anticipating the instant claim. Additionally, compounds found by the screening method are disclosed by Friddle et al. to be useful as pharmaceutical reagents in therapeutic treatment of mental, biological, or medical disorders and disease (see paragraph spanning columns 10-11), thus anticipating the production of therapeutic compounds as in instant claim 11. Accordingly, the rejection of claims 9-11 as being anticipated by the teachings of the '352 patent to Friddle et al. is maintained.

New Claim Rejections, Necessitated by Amendment

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "and inhibits leukocyte activation" in claim 9, step d, renders the claim ambiguous and indefinite because it is not clear if Applicant means that 1) the inhibition of leukocyte activation was also assessed in the screening assay, in which case the claim is incomplete for omitting the essential step of analyzing leukocyte activity, or rather 2) if the substance that inhibits the exchange activity of the polypeptide would be a substance suitable for inhibition of leukocyte activation. The metes and bounds of the claim thus cannot be determined.

Conclusion

Claims 1, 3-8 and 19-21 are subject to allowability. Claims 9-11 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on Monday-Friday 9AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C. Kemmerer

Kimberly Ballard, Ph.D.
March 26, 2007

ELIZABETH C. KEMMERER, PH.D.
PRIMARY EXAMINER